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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,588	11/29/2001	Chen Xing Su	10209.353	6233

21999 7590 05/20/2003

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/997,588	Su et al.
Examiner	**Art Unit**
Patricia Patten	1654

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 1, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1 and 4-28* is/are pending in the application.

4a) Of the above, claim(s) *13-23, 27, and 28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4-12, and 24-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 5/1/03 has been entered.

Claims 1 and 4-28 are pending in the application. Claims 13-23 and 27-28 were withdrawn from further consideration on the merits (Please see Paper No's 9 and 4).

Claims 1, 4-12 and 24-26 have been presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Arguments found in the Amendment filed concurrently with the RCE on 5/8/03 (Paper No.11) pertaining solely to the previous rejections are moot in light of the new rejections *infra*.

Claim Rejections - 35 USC § 112

Claim 25 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25 states '...wherein said processed *Morinda citrifolia* further comprises an additional ingredient that works in conjunction with said Morinda citrifolia.....' It does not appear that there was any disclosure as originally filed which was directed toward the addition of an ingredient which 'works in conjunction' with *Morinda citrifolia*. Thus, this is considered New Matter.

It is suggested that the New Matter be deleted from the claims in order to overcome this rejection. It is noted that the claim was examined on the merits as it stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mumford (1998) in view of Brock et al. (1991) and in view of Gagnon (1997).

Mumford (1998) reported that noni juice (*Morinda citrifolia*) was well known and marketed as a nutritional/medicinal product (p.1). Mumford specifically reported that Keren Swift began taking two ounces of noni juice per day after she noticed a change in migraine headaches (p.1). Because the article taught 'noni juice' and because the article did not specifically mention that the juice had been 'dried or powdered', it is deemed that the 'juice' to which the article is referring is the liquid squeezed from the *M.citrifolia* fruit, especially absent sufficient evidence to the contrary. It is further deemed that because the article recited 'juice' that the juice was 100% *M.citrifolia* juice.

Mumford (1998) did not specifically teach wherein the *M.citrifolia* juice was pasteurized, where the juice was taken on an empty stomach, the addition of sweeteners or carriers to the juice, or a method for manufacturing the juice.

Milk and juices are routinely pasteurized in order to reduce the amount of bacterial contaminants as well as preserve the beverages for longer amounts of time according to Brock et al. (1991). Specifically, Brock et al. taught that pasteurization was found applicable to 'wine, beer, cider, vinegar, milk, and countless other perishable beverages, foods and organic products' (p.334).

Gagnon (1997) suggested '...taking extracts between meals, apart from food, because that is when they are more easily absorbed by the body. This way ,extracts enter the bloodstream readily and immediately start the healing process' (p.27).

One of ordinary skill in the art would have been motivated to have pasteurized the noni juice as disclosed by Mumford (1998) in order to have prolonged the shelf life of the juice. Brock et al. made it clear that pasteurization of beverages was common,

routine practice in the art of beverage making, and well within the purview of the ordinary artisan.

The ordinary artisan would have been motivated to have ingested the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

One of ordinary skill in the art would have been motivated to have added carriers and sweeteners to noni juice in order to have formulated noni juice compositions containing varying percentages of active ingredients (i.e., 'regular' -vs- 'extra strength') as well as for mere ease of delivery. It was routine in the art of pharmacology to admix active ingredients with carriers, colorings and sweeteners for example. Carriers were an advantageous means of diluting active ingredients to necessary dosage ranges. Further, sweeteners and colorings would not have changed the medicinal qualities of the noni.

The language 'inhibiting, preventing and reversing cell membrane disruption' is merely an intrinsic property of the method which would have naturally manifested as a result of drinking the juice.

Specific limitations regarding harvesting, cleaning, or wherein the juice was separated from the solids of the fruit or wherein the fruit is mixed with a sweetener does not materially change the method. The term 'juice,' as defined by Webster's Dictionary, means 'the liquid part of a plant, fruit, or vegetable.' Thus, it is deemed that the juice disclosed by Mumford was the liquid of the fruit which had been separated from solids such as the seeds and the peel.

As stated in the previous Office Action, although the reference does not teach wherein the noni fruit is harvested when it is at least one inch long and twelve inches in diameter, the Examiner deems that the fruit, containing intrinsic phytochemicals, would have contained these phytochemcials (active ingredients) at most of the growing stages of the fruit. The Examiner cannot find any evidence within the Instant specification which clearly indicates that the harvesting limitations found in the claims materially change the characteristics of noni. Thus, it is deemed that the method for harvesting *does not change the method* since the juice is substantially the same juice as described by Mumford especially lacking clear, credible evidence to the contrary.

Further, harvesting limitations such as separating spoiled fruit, and placing the harvested fruit in a plastic container, does not materially change the method for scavenging lipid hydroperoxides. Applicants are *merely reciting pre-operative steps* which do not change the method for reducing cellular damage.

It is further noted that the ordinary artisan would have recognized that *M.citrifolia* juice, and a *M.citrifolia* juice which had come from a concentrate (i.e., reconstituted) would have been substantially the same product. It is deemed that a 'reconstituted' *M.citrifolia* juice, and a crude *M.citrifolia* juice would not be distinguishable from each other since concentration and 'reconstitution' are merely the subtraction and addition of water. Therefore, claim 12 which states that the method includes *M.citrifolia* juice which was obtained 'without drying or powdering' combined with *M.citrifolia* juice which was reconstituted would not have materially changed the composition nor the medicinal effects of the *M.citrifolia* juice.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mumford (1998) in view of Brock et al. (1991) and in view of Gagnon (1997) as applied to claims 1, 4-12, 24 and 26 above, and further in view of Weil (2000).

The teachings of Mumford, Brock et al. and Gagnon were discussed *supra.* None of the references specifically taught combining *M.citrifolia* juice with an additional ingredient which inhibited, prevented or reversed lipid peroxidation.

Weil (2000) reporting for the Northern Echo taught a product named 'Premium Noniplus' combined *M.citrifolia* with aloe and elderberry(p.2). Weil reported that elderberry was rich in antioxidants (p.2).

One of ordinary skill in the art would have been motivated to have combined pasteurized *M.citrifolia* juice with another antioxidant containing juice such as elderberry juice in order to have increased the total amount of ingested antioxidants thereby providing an additive antioxidant (inhibition of lipid peroxidation) effect.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

May 15, 2003

Patricia Patten